

EXPLANATORY STATEMENT

Therapeutic Goods Act 1989

Therapeutic Goods Legislation Amendment (Standards for Labels—International Harmonisation of Ingredient Names) Order 2023

The *Therapeutic Goods Act 1989* (“the Act”) provides for the establishment and maintenance of a national system of controls for the quality, safety, efficacy and timely availability of therapeutic goods that are used in, or exported from, Australia. The Act is administered by the Therapeutic Goods Administration (“the TGA”) within the Australian Government Department of Health and Aged Care (“the Department”).

Subsection 10(1) of the Act relevantly provides that the Minister may, by legislative instrument, make an order determining that matters specified in the order constitute a standard for therapeutic goods or a class of therapeutic goods identified in the order. Subsection 10(2) provides that an order establishing a standard for therapeutic goods may be specified by reference to, among other matters, the quality of the goods or the procedures to be carried out in the manufacture of the goods. Relevantly, however, an order may also require that the goods be labelled or packaged in a specified manner. Subsection 10(3A) of the Act provides that the Minister may, by legislative instrument, vary or revoke an order made under subsection 10(1) of the Act.

Importantly, a person who imports, exports, or supplies therapeutic goods that do not conform to an applicable standard may be subject to offence and civil penalty provisions in sections 14 and 14A of the Act. The Secretary may, however, give consent in writing in relation to the importation, exportation, or supply of therapeutic goods that do not conform to an applicable standard, in accordance with those sections.

The *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines* (“TGO 91”), and the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* (“TGO 92”), are made under section 10 of the Act. Collectively, they mandate the information that must be displayed on the labels of medicines that are supplied, or for supply, in Australia, and the format and placement in which that information must be presented, to contribute to the safe and quality use of medicines by Australian consumers and healthcare professionals.

The *Therapeutic Goods Legislation Amendment (Standards for Labels—International Harmonisation of Ingredient Names) Order 2023* (“the Amendment Order”) is a legislative instrument made under subsection 10(1) of the Act. It amends TGO 91 and TGO 92 to implement the transition period within which sponsors of medicines containing certain active ingredients must update their medicine labels to reflect the end of the International Harmonisation of Ingredient Names (“IHIN”) dual labelling period.

Background

Standards made under subsection 10(1) of the Act may relate to any matter that is relevant to the quality, safety, or efficacy of a therapeutic good, and generally, a therapeutic good must not be supplied in Australia if it does not conform to an applicable standard. Paragraph 10(2)(c) of the Act states that an order establishing a standard for therapeutic goods may require that therapeutic goods, or a class of therapeutic goods identified in the order, be

labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

TGO 91 and TGO 92 are made under subsection 10(1) of the Act. TGO 91 applies to medicines that are supplied, or for supply, in Australia that are of a kind specified in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990* (“the Regulations”), save for those that are expressly excluded by subparagraphs 3(1)(a)(i) to (iv) of TGO 91. Relevantly, TGO 91 applies to medicines that contain substances listed in Schedule 4 (prescription-only medicines) and Schedule 8 (controlled drugs) to the current Poisons Standard, as well as vaccines, radiopharmaceuticals, and some radio contrast agents. TGO 92 applies to all other medicines that are supplied, or for supply in, Australia, other than those that are specified in subsection 5(1) of that order.

Subsection 8(1) of both TGO 91 and TGO 92 mandates the information that must be included on the label of a medicine. This includes, for example, the name of the medicine, the names and quantity or proportion of all active ingredients in the medicine, the batch number and expiry date of the medicine, and the applicable storage solutions. However, recognising that many medicines have more than one label, or different panels within one label, subsection 9(1) of TGO 91 and TGO 92 specifies the most important information that must be displayed on the ‘*main label*’ of the medicine (as that term is defined in section 6 of each order), with the remaining mandatory information to be displayed on the other labels or panels.

Main label must display the name(s) of any active ingredient(s) in a medicine

An ingredient is an active ingredient of a medicine if it is a therapeutically active component in the medicine’s final formulation that is responsible for its physiological or pharmacological actions. In accordance with subsection 9(1) of TGO 91 and TGO 92, the names of all active ingredients in a medicine, together with their quantity or proportion, must be displayed on the main label of the medicine.

Section 6 of TGO 91 and TGO 92 defines the term ‘*name of an active ingredient*’ as the name of the active ingredient that is accepted for inclusion in the Australian Approved Names List (“AANL”). The AANL, which is defined in the Regulations as the document entitled ‘*Australian Approved Names List for Therapeutic Substances*’, as in force from time to time and published by the TGA, is a repository of TGA-approved names to identify substances used in therapeutic goods. The purpose of the AANL is to ensure that only one name is used to specify a substance (to avoid confusion), that the name clearly and unambiguously identifies the substance (for identification and testing purposes), and that substance names remain consistent with international conventions. Approved ingredient names are included in the ‘Ingredients Table’ in the AANL.

The effect of subsection 9(1) of TGO 91 and TGO 92, read together with section 6 of those orders, is that when displaying the names of any active ingredients on the label(s) of a medicine, sponsors must ensure that the ingredient names accurately reflect those that are specified in the AANL.

International harmonisation of ingredient names

In 2016, the TGA updated the names of approximately 300 medicine ingredients in the AANL to align with the names for those ingredients that are used internationally. The purpose of this IHIN process was to reduce confusion for Australian consumers and

healthcare professionals who travel internationally, health professionals who have trained overseas, and for people trying to access medicine information online. Harmonisation of ingredient names has also occurred in some other countries, including the United Kingdom in 2003 and New Zealand in 2008.

Sponsors were given four years to update their medicine labels and their Product Information (“PI”) and Consumer Medicine Information (“CMI”) documents. This transition period ended on 30 April 2020, meaning that affected medicines have, since 1 May 2020, been required to reflect the updated ingredient names on their labels and supporting documents such as PI and CMI leaflets.

However, certain active ingredient name changes were identified as being of higher clinical significance, principally because the new sole ingredient name bears no resemblance to the old ingredient name (for example, the active ingredient ‘benzhexol’ was renamed ‘trihexyphenidyl’). From 1 May 2020, sponsors of medicines containing such ingredients have been required to display both the new and old names of the ingredient (“dual labelling”), to help consumers and health practitioners become familiar with the new ingredient name. These active ingredients (“IHIN dual labelled ingredients”) are specified in Schedule 2 to TGO 91 and TGO 92.

In accordance with subsection 9(5) of TGO 91, and paragraph 9(7)(a) of TGO 92, the names of any active ingredients in a medicine must, generally, be displayed on the main label of the medicine in a text size of not less than 3.0 millimetres. However, to allow for the length of IHIN dual labelled ingredient names, subsection 9(9) of TGO 91 and TGO 92 permit such ingredients to be included on the main label of a medicine in a smaller minimum text size of 2.5 millimetres, for certain sized medicine containers, until 30 April 2023. Importantly, the exception provided by subsection 9(9) of TGO 92 only applies in relation to medicines that are, or are intended to be, included in the ARTG as registered or provisionally registered goods.

From 1 May 2023, IHIN dual labelled ingredient names will begin to transition to internationally harmonised sole names. Most ingredients will be updated to sole names in the AANL by the TGA on 1 May 2023, while some ingredients will have an extended ‘dual labelling’ period before transitioning to sole names from 1 May 2025, and other ingredients have no planned transition to sole names.

Purpose

The purpose of the Amendment Order is to implement two three-year transition periods within which the sponsors of medicines containing IHIN dual labelled ingredient names are permitted to continue displaying those ingredient names (on the main labels of their medicines) in the dual labelling format. Therefore, although medicine labels are required to reflect ingredient names as included in the AANL, when the AANL is updated to reflect sole ingredient names, certain ingredients will be permitted to continue to be labelled with their IHIN dual labelled ingredient name for a particular specified transition period.

The implementation of two separate transition periods reflects the fact that:

1. the TGA will update the majority of IHIN dual labelled ingredient names in the AANL on 1 May 2023 – these ingredients may continue to be dual labelled until 30 April 2026 and must be sole named from 1 May 2026; and

2. medicines containing certain ingredients must continue to be labelled with the dual labelled ingredient names until 30 April 2025, and the TGA will update the AANL for these ingredients on 1 May 2025. These ingredients will then be permitted to be dual labelled or sole named until 30 April 2028 and, from 1 May 2028, these ingredients must be sole named. The TGA's decision to delay its updates to these IHIN dual labelled ingredients is intended to address concerns raised by stakeholders that there is currently insufficient familiarity across the Australian healthcare industry in relation to the sole names of these ingredients.

It has also been identified that some IHIN dual labelled ingredients should remain as such indefinitely, on the basis that additional time for education is likely insufficient to address safety concerns associated with ingredient name changes. For example, the similarity in spelling between the IHIN dual labelled ingredient mercaptamine (cysteamine), and the ingredient mercaptopurine, is such that there is a risk of selection error by health care professionals. These IHIN dual labelled ingredient names will remain as is in the AANL so medicines containing such ingredient will need to continue to have the IHIN dual labelled ingredient name on labels.

The Amendment Order achieves this objective, principally, by amending Schedule 2 to TGO 91 and TGO 92 to comprise three distinct parts. IHIN dual labelled ingredient names that are specified in new Part 1 of Schedule 2 ("Part 1 Ingredients") are permitted to remain in the dual labelling format on medicine labels until 30 April 2026, and must be sole named from 1 May 2026. IHIN dual labelled ingredient names that are specified in new Part 2 of Schedule 2 ("Part 2 Ingredients") must remain in the dual labelling format on medicine labels until 1 May 2025, and are permitted to remain in this format until 30 April 2028, but must be sole named from 1 May 2028. This is even though the AANL will be updated on 1 May 2023 to reflect the sole name of Part 1 Ingredients and on 1 May 2025 for Part 2 Ingredients. IHIN dual labelled ingredient names that are specified in new Part 3 of Schedule 2 ("Part 3 Ingredients") will remain in the dual labelling format in the AANL so medicine labels will need to reflect the dual labelling format indefinitely.

Consequentially, the Amendment Order also makes several amendments to section 9 of TGO 91 and TGO 92. In particular, it inserts into both orders:

- a new subsection 9(11), which states that a Part 1 Ingredient, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient, as specified in that Part, before 1 May 2026; and
- a new subsection 9(13), which states that a Part 2 Ingredient, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient, as specified in that Part, before 1 May 2028.

In the avoidance of doubt, new subsections 9(12) and 9(14) of both orders also clarify that, on or after 1 May 2026 and 1 May 2028, respectively, Part 1 Ingredients and Part 2 Ingredients must be included on the main label of a medicine containing those ingredients in accordance with the AANL.

Finally, the Amendment Order repeals and replaces subsection 9(10) of TGO 91 and TGO 92, principally to extend the application of the minimum text size allowance provided by subsection 9(9) of those orders for the duration of each of the two new transition periods for Part 1 Ingredients and Part 2 Ingredients, and indefinitely for Part 3 Ingredients.

Consultation

The Office of Impact Analysis has advised that the preparation of a policy impact analysis is not required in relation to the creation of the Amendment Order as it is unlikely to have more than a minor regulatory impact (OBPR23-04347).

Between November and December 2022, the TGA conducted a six-week public consultation on whether health professionals, consumers, and members of industry were ready for the dual labelling period to end for all IHIN dual labelled ingredient names on 1 May 2023. The TGA also sought feedback from stakeholders in relation to its proposal to transition from the IHIN dual labelling period to the use of sole ingredient names on medicine labels, and PI and CMI documents, within a specified timeframe. To raise awareness, the TGA notified approximately 225 stakeholders of the consultation period, including sponsors of medicines containing dual labelled ingredients. Thirty-four respondents provided feedback.

The majority of consultation respondents indicated that at least some active ingredient names should remain dual labelled for an extended period, mainly due to impacts of the COVID-19 pandemic on healthcare professionals, and safety issues such as similarity between ingredient names, as reasons in support of an extended dual labelling period. These concerns formed the impetus behind the implementation of two separate transition periods for particular ingredients, as well as the TGA's decision to not update the names of a small number of ingredients.

Further, the majority of consultation respondents supported the TGA's proposal to implement a transition period that requires sponsors to update their medicine labels, within a specified period of time, to reflect the sole names of ingredients contained within their medicines (as approved for use by the TGA in the AANL).

Two three-year transition periods attempts to accommodate all stakeholder preferences, while still ensuring a consistent and timely move from IHIN dual labelling.

Details of the Amendment Order are set out in **Attachment A**.

The Amendment Order is compatible with human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

The Amendment Order is a disallowable legislative instrument for the purposes of the *Legislation Act 2003* and commences on 30 April 2023.

Attachment A

Details of the *Therapeutic Goods Legislation Amendment (Standards for Labels—International Harmonisation of Ingredient Names) Order 2023*

Section 1 Name

This section provides that the name of the instrument is the *Therapeutic Goods Legislation Amendment (Standards for Labels—International Harmonisation of Ingredient Names) Order 2023* (“the Amendment Order”).

Section 2 Commencement

This section provides that the Amendment Order commences on 30 April 2023.

Section 3 Authority

This section provides that the legislative authority for making the Amendment Order is section 10 of the *Therapeutic Goods Act 1989* (“the Act”).

Section 4 Schedules

Section 4 provides that each instrument specified in a Schedule is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to this instrument has effect according to its terms.

The Amendment Order makes amendments to the:

- *Therapeutic Goods Order No. 91 – Standard for labels of prescription and related medicines*; and
- *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines*.

Schedule 1 – Amendments

Items 1 and 4 - Subsection 9(10)

Items 1 and 4 of Schedule 1 to the Amendment Order amend subsection 9(10) of TGO 91 and TGO 92, excluding the note to those subsections, to provide that subsection 9(9) of TGO 91 and TGO 92 does not apply:

- where the medicine is supplied in a small container or a very small container; or
- where the medicine is not supplied in a small container or a very small container and is labelled in accordance with subsection 9(11) and Part 1 of Schedule 2—after 30 April 2026; or
- where the medicine is not supplied in a small container or a very small container and is labelled in accordance with subsection 9(13) and Part 2 of Schedule 2—after 30 April 2028.

Items 2 and 5 of Schedule 1 to the Amendment Order add to the end of section 9 of TGO 91 and TGO 92:

- subsection 9(11), which specifies that an active ingredient specified in Part 1 of Schedule 2, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient as specified in that Part for medicine released for supply before 1 May 2026;
- subsection 9(12), which specifies that, to avoid doubt, an active ingredient specified in Part 1 of Schedule 2 must be included on the main label of a medicine containing that ingredient in accordance with the Australian Approved Names List (“the AANL”) for medicine released for supply on or after 1 May 2026;
- subsection 9(13), which specifies that an active ingredient specified in Part 2 of Schedule 2, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient as specified in that Part for medicine released for supply before 1 May 2028;
- subsection 9(14), which specifies that, to avoid doubt, an active ingredient specified in Part 2 of Schedule 2 must be included on the main label of a medicine containing that ingredient in accordance with the AANL for medicine released for supply on or after 1 May 2028.

Items 3 and 6 of Schedule 1 to the Amendment Order repeal and replace Schedule 2 to TGO 91 and TGO 92, with new Schedule 2 divided into three Parts:

- Part 1, which specifies the names of International Harmonisation of Ingredient Names (“IHIN”) dual labelled ingredients that are permitted to be displayed, on the main label of a medicine that contains those ingredients, in the dual labelling format (as specified in the table) from 1 May 2023 until 30 April 2026 (even though the AANL will be updated to reflect the sole name); and
- Part 2, which specifies the names of IHIN dual labelled ingredients that are permitted to be displayed, on the main label of a medicine that contains those ingredients, in the dual labelling format (as specified in the table) from 1 May 2025 until 30 April 2028 (even though the AANL will be updated on 1 May 2025 to reflect the sole name); and
- Part 3, which specifies the names of IHIN dual labelled ingredients that will remain in the dual labelled format in the AANL and must be labelled in accordance with the AANL, but may continue to be in the text sized permitted in subsection 9(9).

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Therapeutic Goods Legislation Amendment (Standards for Labels—International Harmonisation of Ingredient Names) Order 2023

This disallowable legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The *Therapeutic Goods Order No. 91 - Standard for labels of prescription and related medicines* (“TGO 91”), and the *Therapeutic Goods Order No. 92 – Standard for labels of non-prescription medicines* (“TGO 92”), are made under section 10 of the *Therapeutic Goods Act 1989* (“the Act”). Collectively, they mandate the information that must be displayed on the labels of medicines that are supplied, or for supply, in Australia, and the format and placement in which that information must be presented, to contribute to the safe and quality use of medicines by Australian consumers and healthcare professionals.

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Background

Standards made under subsection 10(1) of the Act may relate to any matter that is relevant to the quality, safety, or efficacy of a therapeutic good, and generally, a therapeutic good must not be supplied in Australia if it does not conform to an applicable standard. Paragraph 10(2)(c) of the Act states that an order establishing a standard for therapeutic goods may require that therapeutic goods, or a class of therapeutic goods identified in the order, be labelled or packaged in a manner, or kept in containers that comply with requirements, specified in the order.

TGO 91 and TGO 92 are made under subsection 10(1) of the Act. TGO 91 applies to medicines that are supplied, or for supply, in Australia that are of a kind specified in Part 1 of Schedule 10 to the *Therapeutic Goods Regulations 1990* (“the Regulations”), save for those that are expressly excluded by subparagraphs 3(1)(a)(i) to (iv) of TGO 91. Relevantly, TGO 91 applies to medicines that contain substances listed in Schedule 4 (prescription-only medicines) and Schedule 8 (controlled drugs) to the current Poisons Standard, as well as vaccines, radiopharmaceuticals, and some radio contrast agents. TGO 92 applies to all other medicines that are supplied, or for supply in, Australia, other than those that are specified in subsection 5(1) of that order.

Subsection 8(1) of both TGO 91 and TGO 92 mandates the information that must be included on the label of a medicine. This includes, for example, the name of the medicine, the names and quantity or proportion of all active ingredients in the medicine, the batch number and expiry date of the medicine, and the applicable storage solutions. However, recognising that many medicines have more than one label, or different panels within one label, subsection 9(1) of TGO 91 and TGO 92 specifies the most important information that must be displayed on the ‘*main label*’ of the medicine (as that term is defined in section 6 of each order), with the remaining mandatory information to be displayed on the other labels or panels.

An ingredient is an active ingredient of a medicine if it is a therapeutically active component in the medicine’s final formulation that is responsible for its physiological or pharmacological actions. In accordance with subsection 9(1) of TGO 91 and TGO 92, the names of all active ingredients in a medicine, together with their quantity or proportion, must be displayed on the main label of the medicine.

Section 6 of TGO 91 and TGO 92 defines the term ‘*name of an active ingredient*’ as the name of the active ingredient that is accepted for inclusion in the Australian Approved Names List (“AANL”). The AANL, which is defined in the Regulations as the document entitled ‘*Australian Approved Names List for Therapeutic Substances*’, as in force from time to time and published by the TGA, is a repository of approved names to identify substances used in therapeutic goods. The purpose of the AANL is to ensure that only one name is used to specify a substance (to avoid confusion), that the name clearly and unambiguously identifies the substance (for identification and testing purposes), and that substance names remain consistent with international conventions. Approved ingredient names are included in the ‘Ingredients Table’ in the AANL.

The effect of subsection 9(1) of TGO 91 and TGO 92, read together with section 6 of those orders, is that when displaying the names of any active ingredients on the label(s) of a medicine, sponsors must ensure that the ingredient names accurately reflect those that are specified in the AANL.

In 2016, the TGA updated the names of approximately 300 medicine ingredients in the AANL to align with the names for those ingredients that are used internationally. The purpose of this IHIN process was to reduce confusion for Australian consumers and healthcare professionals who travel internationally, health professionals who have trained overseas, and for people trying to access medicine information online. Harmonisation of ingredient names has also occurred in some other countries, including the United Kingdom in 2003 and New Zealand in 2008.

Sponsors were given four years to update their medicine labels and their Product Information (“PI”) and Consumer Medicine Information (“CMI”) documents. This transition period ended on 30 April 2020, meaning that affected medicines have, since 1 May 2020, been required to reflect the updated ingredient names on their labels and supporting documents such as PI and CMI leaflets.

However, certain active ingredient name changes were identified as being of higher clinical significance, principally because the new sole ingredient name bears no resemblance to the old ingredient name (for example, the active ingredient ‘benzhexol’ was renamed ‘trihexyphenidyl’). From 1 May 2020, sponsors of medicines containing such ingredients have been required to display both the new and old names of the ingredient (“dual labelling”), to help consumers and health practitioners become familiar with the new ingredient name.

These active ingredients (“IHIN dual labelled ingredients”) are specified in Schedule 2 to TGO 91 and TGO 92.

In accordance with subsection 9(5) of TGO 91, and paragraph 9(7)(a) of TGO 92, the names of any active ingredients in a medicine must, generally, be displayed on the main label of the medicine in a text size of not less than 3.0 millimetres. However, to allow for the length of IHIN dual labelled ingredients, subsection 9(9) of TGO 91 and TGO 92 permit such ingredients to be included on the main label of a medicine in a smaller minimum text size of 2.5 millimetres, for certain sized medicine containers, until 30 April 2023. Importantly, the exception provided by subsection 9(9) of TGO 92 only applies in relation to medicines that are, or are intended to be, included in the ARTG as registered or provisionally registered goods.

From 1 May 2023, IHIN dual labelled ingredient names will transition to internationally harmonised sole names, where the TGA will update most to sole names from 1 May 2023 while other ingredients will have an extended ‘dual labelling’ period before transitioning to sole names or have no planned transition to sole names.

Purpose

The purpose of the Amendment Order is to implement two three-year transition periods within which the sponsors of medicines containing IHIN dual labelled ingredient names are permitted to continue displaying those ingredient names (on the main labels of their medicines) in the dual labelling format. Therefore, although medicine labels are required to reflect ingredient names as included in the AANL, when the AANL is updated to reflect sole ingredient names on 1 May 2023, certain ingredients will be permitted to continue to be labelled with their IHIN dual labelled ingredient name for a particular specified transition period.

The implementation of two separate transition periods reflects the fact that, while the TGA will update the majority of IHIN dual labelled ingredient names in the AANL on 1 May 2023, medicines containing certain ingredients must continue to be labelled with the dual labelled ingredient names until 1 May 2025. The TGA’s decision to delay its updates to the names of some of the IHIN dual labelled ingredients is intended to address concerns raised by stakeholders that there is currently insufficient familiarity across the Australian healthcare industry in relation to the sole names of these ingredients. This is particularly so with respect to the latter cohort of IHIN dual labelled ingredients (that is, those with names that will not be updated until 1 May 2025).

It has also been identified that some IHIN dual labelled ingredients should remain as such indefinitely, on the basis that additional time for education is likely insufficient to address safety concerns associated with ingredient name changes. For example, the similarity in spelling between the IHIN dual labelled ingredient mercaptamine (cysteamine), and the ingredient mercaptopurine, is such that there is a risk of selection error by health professionals. The IHIN dual labelled ingredient names will remain as is in the AANL so medicines containing such ingredient will need to continue to have the IHIN dual labelled ingredient name on labels.

The Amendment Order achieves this objective, principally, by amending Schedule 2 to TGO 91 and TGO 92 to comprise three distinct parts. IHIN dual labelled ingredient names that are specified in new Part 1 of Schedule 2 (“Part 1 Ingredients”) are permitted to remain

in the dual labelling format on medicine labels until 30 April 2026. IHIN dual labelled ingredient names that are specified in new Part 2 of Schedule 2 (“Part 2 Ingredients”) must remain in the dual labelling format on medicine labels until 1 May 2025, and are permitted to remain in this format until 30 April 2028. This is even though the AANL will be updated on 1 May 2023 to reflect the sole name of Part 1 Ingredients and on 1 May 2025 for Part 2 Ingredients. IHIN dual labelled ingredient names that are specified in new Part 3 of Schedule 2 (“Part 3 Ingredients”) will remain in the dual labelling format in the AANL so medicine labels will need to reflect the dual labelling format indefinitely.

Consequentially, the Amendment Order also makes several amendments to section 9 of TGO 91 and TGO 92. In particular, it inserts into both orders:

- a new subsection 9(11), which states that a Part 1 Ingredient, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient, as specified in that Part, before 1 May 2026; and
- a new subsection 9(13), which states that a Part 2 Ingredient, either alone or in combination with any other descriptors, may be included on the main label of a medicine containing that ingredient, as specified in that Part, before 1 May 2028.

In the avoidance of doubt, new subsections 9(12) and 9(14) of both orders also clarify that, on or after 1 May 2026 and 1 May 2028, respectively, Part 1 Ingredients and Part 2 Ingredients must be included on the main label of a medicine containing those ingredients in accordance with the AANL.

Finally, the Amendment Order repeals and replaces subsection 9(10) of TGO 91 and TGO 92, principally to extend the application of the minimum text size allowance provided by subsection 9(9) of those orders for the duration of each of the two new transition periods for Part 1 Ingredients and Part 2 Ingredients, and indefinitely for Part 3 Ingredients.

Human rights implications

The instrument engages the right to health in Article 12 of the International Covenant on Economic, Social and Cultural Rights (“the ICESCR”). Article 12 of the ICESCR promotes the right of all individuals to enjoy the highest attainable standard of physical and mental health, and includes an obligation to take reasonable measures within available resources to progressively secure broader enjoyment of the right.

In *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12)* (2000), the United Nations Committee on Economic, Social and Cultural Rights states that health is a ‘fundamental human right indispensable for the exercise of other human rights’, and that the right to health is not to be understood as the right to be healthy, but includes the right to a system of health protection which provides equal opportunity for people to enjoy the highest attainable level of health.

The Amendment Order takes positive steps to promote the right to health by balancing the need for a timely and consistent transition from the IHIN ingredient dual labelling period to the use of new sole ingredient names for affected ingredients, on the one hand, and on the other, clinical and consumer safety risks that are caused by a lack of familiarity across the healthcare industry in relation to the sole names of such ingredients.

The implementation of two new transition periods, within which the sponsors of medicines containing IHIN dual labelled ingredient names must update their medicine labels, ensures that consumers, health practitioners, and members of industry have additional time to familiarise themselves with the sole names of those ingredients. It also provides a date (at the end of the transition period) for when all medicines should be consistently labelled in a manner that is internationally harmonised, to reduce confusion for Australian consumers and healthcare professionals who travel internationally, health professionals who have trained overseas, and for people trying to access medicine information online.

Conclusion

This legislative instrument is compatible with human rights because it promotes the right to health in Article 12 of the ICESCR and does not raise any other human rights issues.